



PTO/SB/08A (08-03)  
Approved for use through 07/31/2008. OMB 0651-0031

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 6

### Complete if Known

Application Number	10/691,125
Filing Date	October 21, 2003
First Named Inventor	Correale, Pierpaolo
Art Unit	To be determined 1653
Examiner Name	To be determined Agnes Riche
Attorney Docket Number	126442-100008

### U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
AR	1	US- 5,626,845	05-06-1997	Yoneda et al.	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
AR	1	WO 00/61612	04-03-2000	Corixa Corp.		
	2	WO 01/81415 A1	04-27-2001	Amgen Inc.		

Examiner Signature	Agnes Riche	Date Considered	12/09/05
--------------------	-------------	-----------------	----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

FORM PTO-1449 (Modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  <div style="text-align: center;"><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></div> (Use several sheets if necessary)  (37 CFR 1.98(b))		Application No.: 10/691,125 Filing Date: October 21, 2003 First Named Inventor: Correale, Pierpaolo Art Unit: To be determined <u>1653</u> Examiner Name: To be determined <u>Agnes Roche</u> Atty Docket No.: 126442-100008 Title: PTH-rP Related Peptide Cancer Therapeutics	
<b>NON PATENT LITERATURE DOCUMENTS</b>			
<b>OTHER DOCUMENTS (Including Author, Title, Date**, Relevant pages, Place of Publication***)</b>			
AR	1.	P. Correale, L. Micheli, MT Del Vecchio, M. Sabatino, R. Petrioli, D. Pozzessere, S. Masili, G. Giorgi, L. Lozzi, P. Neri and G. Francini. A parathyroid-hormone-related-protein (PTH-rP)-specific cytotoxic T cell response induced by in vitro stimulation of tumour-infiltrating lymphocytes derived from prostate cancer metastases, with epitope peptide-loaded autologous dendritic cells and low-dose IL-2. <i>British Journal of Cancer</i> 1722-1730 (2001).	
I	2.	G. Francini, A. Scardino, K. Kosmatopoulos, F. A. Lemonnier, G. Campoccia, M. Sabatino, D. Pozzessere, R. Petrioli, L. Lozzi, P. Neri, G. Fanetti, M.G. Cusi, and P. Correale. High-Affinity HLA-A*02.01 peptides from parathyroid hormone-related protein generate in vitro and in vivo antitumor CTL response without autoimmune side effects. <i>The Journal of Immunology</i> (2002).	
I	3.	P. Correale, M.G. Cusi, M. Sabatino, L. Micheli, D. Pozzessere, C. Nencini, P.E. Valensin, R. Petrioli, G. Giorgi, R. Zurbriggen, R. Gluck, G. Francini. Tumour-associated antigen (TAA)-specific cytotoxic T cell (CTL) response <i>in vitro</i> and in a mouse model, induced by TAA-plasmids delivered by influenza virosomes. <i>European Journal of Cancer</i> 37, 2097-2103 (2001).	
I	4.	L.J. Suva, G.A. Winslow, R.E. H. Wettenhall, R.G. Hammonds, J.M. Moseley, H. Diefenbach-Jagger, C.P. Rodda, B.E. Kemp, H. Rodriguez, E.Y. Chen, P.J. Hudson, T.J. Martin, W.I. Wood. A parathyroid hormone-related protein implicated in malignant hypercalcemia: cloning and expression. <i>Science Reports</i> , Aug. (1987).	
I	5.	R.G. Fenton, D.D. Taub, L.W. Kwak, M.R. Smith, D. L. Longo. Cytotoxic T-cell response and in vivo protection against tumor cells harboring activated ras proto-oncogenes. <i>Journal of the Nat. Cancer Institute</i> , Vol. 85, No. 16, 1294-1302, August (1993)	
I	6.	S. Pascolo, N. Bervas, J.M. Ure, A.G. Smith, F.A. Lemonnier, and B. Perarnau. HLA-A2.1-restricted education and cytolytic activity of CD8 <sup>+</sup> T lymphocytes from $\beta$ 2 microglobulin ( $\beta$ 2m) HLA-A2.1 monochain transgenic H-2D <sup>b</sup> $\beta$ 2m double knockout mice. <i>Journal Exp. Med.</i> , Vol. 185, No. 12, 2043-2051, June (1997).	
I	7.	R.A. Henderson, H. Michel, K. Sakaguchi, J. Shabanowitz, E. Appella, D.F. Hunt, V.H. Engelhard. HLA-A2.1-associated peptides from a mutant cell line: A second pathway of antigen presentation. <i>Science</i> , vol. 225, March (1992).	
I	8.	D.F. Hunt, R.A. Henderson, J. Shabanowitz, K. Sakaguchi, H. Michel, N. Sevilir, A.L. Cox, E. Appella, V.H. Engelhard. Characterization of peptides bound to the Class I MHC Molecule HLA-A2.1 by mass spectrometry. <i>Science</i> , Vol. 255, Issue 5049, 1261-1263, March (1992).	
I	9.	P. Correale, K. Walmsley, C. Nieroda, S. Zaremba, M. Zhu, J. Schlom and K.Y. Tsang. In vitro generation of human cytotoxic T lymphocytes specific for peptides derived from prostate-specific antigen. <i>Journal of the National Cancer Institute</i> , Vol. 89, 293-300 (1997).	
I	10.	P. Correale, K. Walmsley, S. Zaremba, M. Zhu, J. Schlom, K.Y. Tsang. Generation of human cytolytic T lymphocyte lines directed against prostate-specific antigen (PSA) employing a PSA oligopeptide peptide. <i>Journal of National Cancer Institute</i> , 293-300, February (1997).	
I	11.	P. Correale, M. Sabatino, M.G. Cusi, L. Micheli, C. Nencini, D. Pozzessere, R. Petrioli, A. Aquino, L. DeVecchis, M. Turiziani, S.P. Prete, R. Sanguedolce, L. Rausa, G. Giorgi, G. Francini. In vitro generation of cytotoxic T lymphocytes against HLA-A2.1-restricted peptides derived from human thymidylate synthase. <i>Journal of Chemotherapy</i> . 519-26; October (2001).	
I	12.	T. Wolfel, E. Kiehmman, C. Muller, K.H. Schutt, K.H. Meyer zum Buschenfelde and A. Knuth. Lysis of human melanoma cells by autologous cytolytic T cell clones. Identification of human histocompatibility leukocyte antigen A2 as a restriction element for three different antigens. <i>Journal of Experimental Medicine</i> , Vol. 170, 797-810, (1989).	
I	13.	J.P. Eder, P.W. Kantoff, K. Roper, G. Xu, G.J. Bubley, J. Boyden, L. Gritz, G. Mazzara, W.K. Oh, P. Arlen, K.Y. Tsang, D. Panicali, J. Schlom, and D.W. Kufe. A Phase I trial of a recombinant vaccinia virus expressing prostate-specific antigen in advanced prostate cancer. <i>Clinical Cancer Research</i> , Vol. 6, 1632-1638, May (2000).	
I	14.	C. Brander, O.O. Yang, N.G. Jones, Y. Lee, P. Goulder, R.P. Johnson, A. Trocha, D. Colbert, C. Hay, S. Buchbinder, C.C. Bergmann, H.J. Zweerink, S. Wolinsky, W.A. Blattner, S.A. Kalams and B.D. Walker. Efficient processing of the immunodominant, HLA-A *0201-restricted human immunodeficiency virus type 1 cytotoxic T-lymphocyte epitope despite multiple variations in the epitope flanking sequences. <i>Journal of Virology</i> , 10191-10198, December (1999).	
I	15.	M.R. Betts, J.P. Casazza, B.A. Patterson, S. Waldrop, W. Trigona, Tong-Ming Fu, F. Kern, L.J. Picker, and R.A. Koup. Putative Immunodominant human immunodeficiency virus-specific CD8 <sup>+</sup> T-cell responses cannot be predicted by major histocompatibility complex class I haplotype. <i>Journal of Virology</i> , 9144-9151, October (2000).	
I	16.	S. Pascolo, N. Bervas, J.M. Ure, A.G. Smith, F.A. Lemonnier, and B. Perarnau. HLA-A2.1-restricted education and cytolytic activity of CD8 <sup>+</sup> T lymphocytes from $\beta$ 2 microglobulin ( $\beta$ 2m) HLA-A2.1 monochain transgenic H-2D <sup>b</sup> $\beta$ 2m double knockout mice. <i>Journal of Experimental Medicine</i> , Vol. 185, No. 12, 2043-2051, June (1997)	
I	17.	K. Dunussi-Joannopoulos. Gene therapy vaccines: guiding the immune system to fight leukemia. <i>The Journal of the Hellenic Society of Haematology</i> , 124-134, (1999)	
I	18.	A. Zippelius, M.J. Pittet, P. Romero. Dissecting tumor antigen-specific CD8 T cell responses in cancer patients. <i>Ludwig Institute for Cancer Research</i>	
Examiner <u>Agnes B. Roche</u>		Date Considered <u>12/09/05</u>	
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Use several sheets if necessary)

(37 CFR 1.98(b))

Application No.: 10/691,125

Filing Date: October 21, 2003

First Named Inventor: Correale, Pierpaolo

Art Unit: To be determined

Examiner Name: To be determined

Atty Docket No.: 126442-100008

Title: PTH-rP Related Peptide Cancer Therapeutics

**NON PATENT LITERATURE DOCUMENTS**

**OTHER DOCUMENTS (Including Author, Title, Date\*\*, Relevant pages, Place of Publication\*\*\*)**

- |    |     |   |
|----|-----|---|
| AR | 19. | T.E. Sparer, S.G. Wynn, D.J. Clark, J.M. Kaplan, L.M. Cardoza, S.C. Wadsworth, A.E. Smith and L.R. Gooding. Generation of cytotoxic T lymphocytes against immunorecessive epitopes after multiple immunizations with adenovirus vectors is dependent on haplotype. <i>Journal of Virology</i> , 2277-2284, March (1997).  |
|    | 20. | G.R. Mundy and T.A. Guise. Role of parathyroid hormone-related peptide in hypercalcemia of malignancy and osteolytic bone disease. <i>Endocrine-Related Cancer</i> , 15-26, (1998).   |
|    | 21. | T. Takeshita, H. Takahashi, S. Kozlowski, J.D. Ahlers, C.D. Pendleton, R.L. Moore, Y. Nakagawa, K. Yokomuro, B.S. Fox, D.H. Margulies, and J.A. Berzofsky. Molecular analysis of the same HIV peptide functionally binding to both a Class I and a Class II MHC molecule. <i>The American Association of Immunologists</i> , (1995)   |
|    | 22. | V. Tsai, S. Southwood, J. Sidney, K. Sakaguchi, Y. Kawakami, E. Appella, A. Sette, and E. Celis. Identification of subdominant CTL epitopes of the GP100 melanoma-associated tumor antigen by primary in vitro immunization with peptide-pulsed dendritic cells. <i>The Journal of Immunology</i> , Vol. 158: 1796-1802, (1997).  |
|    | 23. | D.M. Pardoll. (Commentary) Inducing autoimmune disease to treat cancer. <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 96, 5340-5342, May (1999).   |
|    | 24. | D. O'Sullivan, T. Arrhenius, J. Sidney, Marie-France Del Guercio, M. Albertson, M. Wall, C. Oseroff, S. Southwood, S.M. Colon, Federico C.A. Gaeta, and A. Sette. On the interaction of promiscuous antigenic peptides with different dr alleles. <i>The Journal of Immunology</i> , Vol. 147, 2663-2669, No. 8, October, (1991).   |
|    | 25. | A. Heiser, P. Dahm, D.R. Yancy, M.A. Maurice, D. Boczkowski, S.K. Nair, E. Gilboa, and J. Vieweg. Human dendritic cells transfected with RNA encoding prostate-specific antigen stimulate prostate-specific CTL responses in vitro. <i>The Journal of Immunology</i> , 164: 5508-5514 (2000).   |
|    | 26. | S.A. Thomson, R. Khanna, J. Gardner, S.R. Burrows, B. Coupar, D.J. Moss and A. Suhrbier. Minimal epitopes expressed in a recombinant polypeptide protein are processed and presented to CD8 <sup>+</sup> cytotoxic T cells: Implications for vaccine design. <i>Proc. Natl. Acad. Sci.</i> , Vol. 92, 5845-5849, June (1995).   |
|    | 27. | J.S. Blanchet, D. Valmori, I. Dufau, M. Ayyoub, C. Nguyen, P. Guillaume, B. Monsarrat, J.C. Carottini, P. Romero, and J.E. Gairin. A new generation of melan-A/MART-1 peptides that fulfill both increased immunogenicity and high resistance to biodegradation: implication for molecular anti-melanoma immunotherapy. <i>The Journal of Immunology</i> , Vol. 167, 5852-5861, (2001).   |
|    | 28. | J. Lu and E. Celis. Use of two predictive algorithms of the world wide web for the identification of tumor-reactive T-cell epitopes. <i>Cancer Research</i> , Vol. 60, 5223-5227, September (2000).   |
|    | 29. | F. Micheletti, A. Canella, S. Vertuani, M. Marastoni, L. Tosi, S. Volinia, S. Traniello, and R. Gavioli. Supra-agonist peptides enhance the reactivation of memory CTL responses. <i>The Journal of Immunology</i> , Vol. 165, 4264-4271 (2000).  |
|    | 30. | K. Kuzushima, N. Hayashi, H. Kimura, and T. Tsurumi. Efficient identification of HLA-A*2402-restricted cytomegalovirus-specific CD8 <sup>+</sup> T-cell epitopes by a computer algorithm and an enzyme-linked immunospot assay. <i>Blood</i> , Vol. 98, No. 6, September (2001).  |
|    | 31. | K. Kyriakos, P. Papadopoulos, N. Suci-Foca, C.S. Hesdorffer, S. Tugulea, A. Maffei, and P.E. Harris. Naturally processed tissue and differentiation state-specific autologous peptides bound by HLA Class I and II molecules of chronic myeloid leukemia blasts. <i>Blood</i> , Vol. 90, No. 12, 4938-4946, December (1997).  |
|    | 32. | I. Kawashima, V. Tsai, S. Southwood, K. Takesako, A. Sette, and E. Celis. Identification of HLA-A3-restricted cytotoxic T lymphocyte epitopes from carcinoembryonic antigen and HER-2/neu by primary in vitro immunization with peptide-pulsed dendritic cells. <i>Cancer Research</i> 59, 431-435, January (1999).   |
|    | 33. | J.H. Kessler, N.J. Beekman, S.A. Bres-Vloemans, P. Verdijk, P.A. van Veelen, A.M. Kloosterman-Joosten, D.C.J. Vissers, G. J.A. ten Bosch, M. G.D. Kester, A. Sijts, J.W. Drifhout, F. Ossendorp, R. Offringa, and C. J.M. Mellef. Efficient identification of novel HLA-A*0201-presented cytotoxic T lymphocyte epitopes in the widely expressed tumor antigen PRAME by proteasome-mediated digestion analysis. <i>Journal of Exp. Med.</i> , Vol. 193, No. 1, 73-88, January (2001). |
|    | 34. | A.K. Sharma, J.J. Kuhns, S. Yan, R.H. Friedline, B. Long, R. Tisch, and E.J. Collins. Class I major histocompatibility complex anchor substitutions alter the conformation of T cell receptor contracts. <i>The Journal of Biological Chemistry</i> , Vol. 276, No. 24, 21443-21449, June (2001).   |
|    | 35. | H. Margalit, J.L. Spouge, J.L. Cornette, K.B. Cease, C. Delisi, and J.A. Berzofsky. Prediction of immunodominant helper T cell antigenic sites from the primary sequence. <i>The Journal of Immunology</i> , Vol. 138, No. 7, 2213-2229, April (1987).  |
|    | 36. | K.C. Parker, M.A. Bednarek, and J.E. Coligan. Scheme for ranking potential HLA-A2 binding peptides based on independent binding of individual peptide side-chains. <i>Journal of Immunology</i> , (1994), 152:163.  |
|    | 37. | E. Keogh, J. Fikes, S. Southwood, E. Celis, R. Chesnut, and A. Sette. Identification of new epitopes from four different tumor-associated antigens: recognition of naturally processed epitopes correlates with HLA-A*0201-binding affinity. <i>The Journal of Immunology</i> , (2001), 167: 787-798.   |

Examiner

James B. Purdie

Date Considered

12/09/05

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Use several sheets if necessary)

(37 CFR 1.98(b))

Application No.: 10/691,125

Filing Date: October 21, 2003

First Named Inventor: Correale, Pierpaolo

Art Unit: To be determined

Examiner Name: To be determined

Atty Docket No.: 126442-100008

Title: PTH-rP Related Peptide Cancer Therapeutics

**NON PATENT LITERATURE DOCUMENTS**

**OTHER DOCUMENTS (Including Author, Title, Date\*\*, Relevant pages, Place of Publication\*\*\*)**

AR	38.	Y. Zhao, B. Gran, C. Piniella, S. Markovic-Plese, B. Hemmer, A. Tzou, L.W. Whitney, W.E. Biddison, R. Martin, and R. Simon. Combinatorial peptide libraries and biometric score matrices permit the quantitative analysis of specific and degenerate interactions between clonotypic TCR and MHC peptide ligands. The Journal of Immunology, (2001), 167: 2130-2141.
	39.	B.M. Carreno, R.V. Turner, W.E. Biddison, and J.E. Coligan. Overlapping epitopes that are recognized by CD8 <sup>+</sup> HLA Class I-restricted and CD4 <sup>+</sup> Class II-restricted cytotoxic T lymphocytes are contained within an influenza nucleoprotein peptide. The Journal of Immunology, Vol. 148, No. 3, 894-899, February (1992).
	40.	S.A. Luyckx-de Bakker, T.D. de Grunijl, R.J. Scheper, J. Wagstaff and H.M. Pinedo. Dendritic cells: a novel therapeutic modality. Annals of Oncology, Vol. 10, 21-77, (1999).
	41.	S. Grabbe, S. Beissert, T. Schwarz, and R.D. Granstein. Dendritic cells as initiators of tumor immune responses: a possible strategy for tumor immunotherapy? Immunology Today, Vol. 16, No. 3, (1995).
	42.	R.M. Steinman, The dendritic cell system and its role in immunogenicity. Annual Review of Immunology, (1991), 9:271-96.
	43.	N. Romani, D. Reider, M. Heuer, S. Ebner, E. Kampgen, B. Eibl, D. Niederwieser, G. Schuler. Generation of mature dendritic cells from human blood. An improved method with special regard to clinical applicability. Journal of Immunological Methods, 196 (1996), 137-151.
	44.	I. Melero, N. Bach, and L. Chen. Minireview: Costimulation, tolerance and ignorance of cytolytic T lymphocytes in immune responses to tumor antigens. Life Sciences, Vol. 60, No. 23, 2035-2041, (1997).
	45.	B.M. Vose and M. Moore. Human tumor-infiltrating lymphocytes: a marker of host response. Seminars in Hematology, Vol. 22, No. 1, 27-40, January (1985).
	46.	A. van Pel, P. van der Bruggen, P.G. Coulie, V.G. Brichard, B. Lethé, B. van den Eynde, C. Uytendaele, J.C. Renauld, and T. Boon. Genes coding for tumor antigens recognized by cytolytic T lymphocytes. Immunological Reviews, (1995), No. 145.
	47.	G. Francini, K.Y. Tsang, G. Campoccia, D. Pozzessere, L. Lozzi, G. Fanetti, and P. Correale. Ex vivo generation and characterization of human cytotoxic T lymphocytes specific for HLA-A2.1 binding peptides derived from parathyroid related hormone peptide (PTH-rP). American Association of Cancer Research, 91 <sup>st</sup> Annual Meeting, April (2000).
	48.	S.A. Rosenberg, J.R. Yannelli, J.C. Yang, S.L. Topalian, D.J. Schwarzenberger, J.S. Weber, D.R. Parkinson, C.A. Seipp, J.H. Einhorn, D.E. White. Treatment of patients with metastatic melanoma with autologous tumor-infiltrating lymphocytes and interleukin 2. Journal of the National Cancer Institute, Vol. 86, No. 15, August (1994).
	49.	S. Markowicz and E.G. Engleman. Granulocyte-macrophage colony-stimulating factor promotes differentiation and survival of human peripheral blood dendritic cells in vitro. The American Society for Clinical Investigation, Inc., Vol. 85, 955-961, March (1990).
	50.	G. Francini, R. Petrioli, A. Manganelli, M. Cintonio, S. Marsili, A. Aquino and S. Mondillo. Weekly chemotherapy in advanced prostatic cancer. Br. Journal of Cancer, Vol. 67, 1430-1436, (1993).
	51.	D. S. Coffey. Prostate Cancer; An overview of an increasing dilemma. Cancer Supplement, Vol. 71, No. 3, February (1993).
	52.	T. Wolfel, E. Klehmann, C. Muller, Klaus-Hermann Schutt, Karl-Hermann Meyer Zum Buschenfelde, and A. Knuth. Lysis of human melanoma cells by autologous cytolytic T cell clones. Identification of human histocompatibility leukocyte antigen A2 as a restriction element for three different antigens. Journal Exp. Med., Vol. 170, 797-810, September (1989).
	53.	S.L. Topalian, D. Solomon, and S.A. Rosenberg. Tumor-specific cytotoxicity by lymphocytes infiltrating human melanomas. The Journal of Immunology, Vol. 142, No. 10, 3174-37-25, May, (1989).
	54.	T.A. Guise, M.D. Parathyroid hormone-related protein and bone metastases. Cancer Supplement, Vol. 80, No. 8, October, (1997).
	55.	R.D. Rubens. Bone metastases - the clinical problem. European Journal of Cancer, Vol. 34, No. 2, 210-213, (1998).
	56.	V. Grill, W. Rankin, and T.J. Martin. Original Paper: Parathyroid hormone-related protein (PTHrP) and hypercalcaemia. European Journal of Cancer, Vol. 34, No. 2, 222-229, (1998).
	57.	G.R. Mundy, M.D. Mechanisms of bone metastasis. Cancer Supplement, Vol. 80, No. 8, October (1997).

Examiner

*Hornes B. Rodde*

Date Considered

*12/69/05*

**EXAMINER:** Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Use several sheets if necessary)

Application No.: 10/691,125

Filing Date: October 21, 2003

First Named Inventor: Correale, Pierpaolo

Art Unit: To be determined

Examiner Name: To be determined

Atty Docket No.: 126442-100008

Title: PTH-rP Related Peptide Cancer Therapeutics

(37 CFR 1.98(b))

**NON PATENT LITERATURE DOCUMENTS**

**OTHER DOCUMENTS (Including Author, Title, Date, Relevant pages, Place of Publication)**

AR	58.	J.J. Yin, K. Selander, J.M. Chirgwin, M. Dallas, B.G. Grubbs, R. Wieser, J. Massague, G.R. Mundy, and T.A. Guise. TGF- $\beta$ signaling blockade inhibits PTHrP secretion by breast cancer cells and bone metastases development. The Journal of Clinical Investigation, Vol. 103, No. 2, January (1999).
	59.	T. Yoneda. Original Paper: Cellular and molecular mechanisms of breast and prostate cancer metastasis to bone. European Journal of Cancer, Vol. 34, No. 2, 240-245, (1998)
	60.	B. Lanske, M. Amling, L. Neff, J. Guiducci, R. Baron, and H.M. Kronenberg. Ablation of the PTHrP gene or the PTH/PTHrP receptor gene leads to distinct abnormalities in bone development. The Journal of Clinical Investigation, Vol. 104, No. 4, August (1999).
	61.	S.J. Vargas, M.T. Gillespie, G.J. Powell, J. Southby, J.A. Danks, J.M. Moseley, and T.J. Martin. Localization of parathyroid hormone-related protein mRNA expression in breast cancer and metastatic lesions by in situ hybridization. Journal of Bone and Mineral Research, Vol. 7, No. 8, (1992).
	62.	J.M. Moseley, M. Kubota, H. Diefenbach-Jagger, R.E.H. Wettenhall, B.E. Kemp, L.J. Suva, C.P. Rodda, P.R. Ebeling, P.J. Hudson, J.D. Zajac, and T.J. Martin. Parathyroid hormone-related protein purified from a human lung cancer cell line. Proc. Natl. Acad. Sci., USA, Vol. 84, 5048-5052, July (1987).
	63.	R. Cibotti, J.M. Kanellopoulos, Jean-Pierre Cabanillos, O. Halle-Panenko, K. Kosmatopoulos, E. Sercarz, and P. Kourilsky. Tolerance to a self-protein involves its immunodominant but does not involve its subdominant determinants. Proc. Natl. Acad. Sci. USA, Vol. 89, 416-420, January (1992).
	64.	G. Murphy, B. Tjoa, H. Ragde, G. Kenny, and A. Boynton. Phase I Clinical Trial: T-cell therapy for prostate cancer using autologous dendritic cells pulsed with HLA-A0201-specific peptides from prostate-specific membrane antigen. The Prostate 29:371-380 (1996).
	65.	P.F. Robbins, and Y. Kawakami. Human tumor antigens recognized by T cells. Current Opinion in Immunology 8:628-636, (1996).
	66.	S. Jung, and H.J. Schluesener. Human T lymphocytes recognize a peptide of single point-mutated, oncogenic ras proteins. Journal Exp. Med., Vol. 173, 273-276, January (1991).
	67.	H. Firat, F. Garcia-Pons, S. Tourdot, S. Pascolo, A. Scardino, Z. Garcia, Marie-Louise Michel, R.W. Jack, G. Jung, K. Kosmatopoulos, L. Mateo, A. Suhrbier, F.A. Lemonnier, and P. Langlade-Demoyen. European Journal of Immunology, 29:3112-3121, (1999).
	68.	K.C. Parker, M.A. Bednarek, and J.E. Coligan. Scheme for ranking potential HLA-A2 binding peptides based on independent binding of individual peptide side-chains. Journal of Immunology, 152:163, (1994).
	69.	D.F. Hunt, R.A. Henderson, J. Shabanowitz, K. Sakaguchi, H. Michel, N. Sevilir, A.L. Cox, E. Appella, V.H. Engelhard. Characterization of peptides bound to the Class I MHC Molecule HLA-A2.1 by mass spectrometry. Science, Vol. 255, 1261-1263, March (1992).
	70.	K. Falk, O. Rotzschke, S. Stevanovic, G. Jung, and Hans-Georg Rammensee. Allele-specific motifs revealed by sequencing of self-peptides eluted from MHC molecules. Nature, Vol. 351, 290-296, May (1991).
	71.	S. Pascolo, N. Bervas, J.M. Ure, A.G. Smith, F.A. Lemonnier, and B. Perarnau. HLA-A2.1-restricted education and cytolytic activity of CD8 <sup>+</sup> lymphocytes from $\beta 2$ microglobulin ( $\beta 2m$ ) HLA-A2.1 monochain transgenic H-2D <sup>b</sup> $\beta 2m$ double knockout mice. Journal Exp. Med., Vol. 185, No. 12, 2043-2051, June (1997).
	72.	Jos G. A. Houbiers, H.W. Nijman, S.H. van der burg, Jan Wouter Drifhout, P. Kenemans, C.J.H. van de Velde, A. Brand, F. Momburg, W.M. Kast, and C.J.M. Melief. In vitro of human cytotoxic T lymphocyte responses against peptides of mutant and wild-type p53. European Journal of Immunology, 23:2072-2077, (1993).
	73.	S.I. Abrams, M.J. Dobrzanski, D.T. Wells, S.F. Stanziale, S. Zaremba, L. Masuelle, J.A. Kantor and J. Schlom. Peptide-specific activation of cytolytic CD4 <sup>+</sup> T lymphocytes against tumor cells bearing mutated epitopes of K-ras p21. European Journal of Immunology, 25:2588-2597, (1995).
	74.	R.G. Fenton, D.D. Taub, L.W. Kwak, M.R. Smith, D.L. Longo. Cytotoxic T-cell response and in vivo protection against tumor cells harboring activated ras proto-oncogenes. Journal of the National Cancer Institute, Vol. 85, No. 16, August (1993).
	75.	E. Keogh, J. Fikes, S. Southwood, E. Celis, R. Chesnut, and A. Sette. Identification of new epitopes from four different tumor-associated antigens: Recognition of naturally processed epitopes correlates with HLA-A*0201-binding affinity. The Journal of Immunology, 167:787-796, (2001).
	76.	V. Cerundolo, J. Alexander, K. Anderson, C. Lamb, P. Cresswell, A. McMichael, F. Gotch, and A. Townsend. Presentation of viral antigen controlled by a gene in the major histocompatibility complex. Nature, Vol. 345, May (1990).
	77.	P. van der Bruggen, C. Traversari, P. Chomez, C. Lurquin, E. De Plaen, B. Van den Eynde, A. Knuth, T. Boon. A gene encoding an antigen recognized by cytolytic T lymphocytes on a human melanoma. Science, Vol. 254, 1643-1647, December (1991).
	78.	N.J. Crowley, T.L. Darrow, M. Ann Quinn-Allen, and H.F. Seigler. MHC-restricted recognition of autologous melanoma by tumor-specific cytotoxic T cells. The Journal of Immunology, Vol. 146, No. 5, 1692-1699, March (1991).

Examiner

*James B. Reddie*

Date Considered

*12/6/05*

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified)  
U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use several sheets if necessary)

(37 CFR 1.98(b))

Application No.: 10/691,125

Filing Date: October 21, 2003

First Named Inventor: Corneale, Pierpaolo

Art Unit: To be determined

Examiner Name: To be determined

Atty Docket No.: 126442-100008

Title: PTH-rP Related Peptide Cancer Therapeutics

**NON PATENT LITERATURE DOCUMENTS**

**OTHER DOCUMENTS (Including Author, Title, Date\*\*, Relevant pages, Place of Publication\*\*\*)**

AR	79.	S.A. Rosenberg, J.C. Yang, D.J. Schwartzentruber, P. Hwu, F.M. Marincola, S.L. Topalian, N.P. Restifo, M.E. Dudley, S.L. Schwarz, P.J. Spiess, J.R. Wunderlich, M.R. Parkhurst, Y. Kawakami, C.A. Seipp, J.H. Einhorn and D.E. White. Nature Medicine, Vol. 4, No. 3, 321-327, March (1998).
J	80.	K.Y. Tsang, S. Zaremba, C.A. Nieroda, M.Z. Zhu, J.M. Hamilton, J. Schlom. Generation of human cytotoxic T cells specific for human carcinoembryonic antigen epitopes from patients immunized with recombinant vaccinia-CEA vaccine. Journal of the National Cancer Institute, Vol. 87, No. 13, July (1995).
J	81.	S.A. Rosenberg, J.C. Yang, D.J. Schwartzentruber, P. Hwu, F.M. Marincola, S.L. Topalian, N.P. Restifo, M. Sznol, S.L. Schwarz, P.J. Spiess, J.R. Wunderlich, C.A. Seipp, J.H. Einhorn, L. Rogers-Freezer, and D.E. White. Impact of cytokine administration on the generation of antitumor reactivity in patients with metastatic melanoma receiving a peptide vaccine. The Journal of Immunology, 163:1690-1695, (1999).